5. 510(K) SUMMARY

APR 15 2009

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: March 9, 2009

510(k) number: K090999

Applicant Information:
BioCardia, Inc.
125 Shoreway Road, Suite B
San Carlos CA 94070

Contact Person
David Snow
Vice President, Research and Development
650-226-0133
dsnow@biocardia.com

Device Information:

Trade Name:	BioCardia Morph® Sheath Guide
Classification:	Class II
Classification Name:	Catheter Introducer

Physical Description:

The BioCardia Morph® Sheath Guide is a single lumen steerable catheter introducer. It is designed to be delivered percutaneously with the use of an internal dilator and advanced to a desired location within the vasculature to facilitate delivery of therapeutic catheters. Steering of the device is accomplished by rotation of a knob on the handle which deflects the distal tip of the catheter shaft. The BioCardia Morph Sheath Guide is supplied with a dilator and includes a hemostasis valve through which the dilator, guidewires, and devices may be passed while minimizing blood loss.

Intended Use:
The BioCardia Morph® Sheath Guide is intended to provide a pathway through which medical instruments, such as balloon dilatation catheters, guidewires, or other therapeutic devices may be introduced into the peripheral vasculature.

Equivalent Devices:
The subject device is substantially equivalent in intended use and/or method of operation to the following devices:

BioCardia Morph® Universal Deflectable Guide Catheter	K042553
Enpath / Bard® Channel Steerable Sheath	K043489
Pinnacle® Destination® Peripheral Guiding Sheath	K080415

Test Results:

Performance

Results of in-vitro and animal testing demonstrate that the BioCardia Morph® Sheath Guide is safe and effective for its intended use.

Biocompatibility

The materials used in the BioCardia Morph® Sheath Guide meet the requirements of ISO 10993-1.

Summary:

Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2009

BioCardia, Inc.
c/o Mr. Morten Simon Christensen
Staff Engineer
Underwriters Laboratories, Inc.
455 E. Trimble Road
San Jose, CA 95131

Re: K090999
BioCardia Morph Sheath Guide
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 1, 2009
Received: April 8, 2009

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: BioCardia Morph® Sheath Guide

Indications for Use:

The BioCardia Morph® Sheath Guide is intended to provide a pathway through which medical instruments, such as balloon dilatation catheters, guidewires, or other therapeutic devices may be introduced into the peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090999

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